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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,655	08/10/2007	Andreas Jungbluth	API-03-15-US	4790

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	PAPER NUMBER
1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,655	JUNGBLUTH ET AL.	
	Examiner	Art Unit	
	GINNY PORTNER	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *52-81* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: sequence conpliance/Notice to Comply.

Claims 52-81 are pending.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) s 52-62, and 67-77 plurality of peptide products that have a shared function but differ in structure, and therefore vary in function and type of effect and a corresponding method of purifying pertussis toxin.

Group II, claim(s) 63-66 drawn to a plurality of methods of making and isolating any type of DNA-peptide fusion product, the methods not being required to make the first appearing invention peptide of claim 52.

Group III, claim(s) s 78-81, drawn to a plurality of DNA-peptide fusion products that evidence different structures, functions and vary in the biological effect based upon the differing chemical structure.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:. (d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c). Each group of inventions is so linked as to form a single general based upon differing chemical structures, the claimed products all not sharing a common core structure. 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for Examination purposes. Accordingly, in most cases, up to ten independent and distinct Nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

In some exceptional cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten. In other cases, applicants may petition pursuant to 37 CFR 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions.

See MPEP § 1850 for treatment of claims containing independent and distinct nucleotide sequences in international applications filed under the Patent Cooperation Treaty (PCT) and national stage applications filed under 35 U.S.C. 371.

If Group I is selected, please select 10 peptides for consideration based upon assigned SEQ ID NO. and the corresponding method of use.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: Group I contains a plurality of species, each species representing a different product based upon SEQ ID NO. Applicant should select 10 species of invention for examination if Group I is selected and the corresponding method of using the peptide.

Group II, recites 4 different species of method that utilize differing reagents, starting materials and resultant products. Select a single method of generating or isolating a DNA-peptide fusion product is Group II is elected.

Group III is directed to a plurality of DNA-peptide fusion products, each differing in structure, function and biological effect. Select a single species from claims 78-81, if this group is selected.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP

§ 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

Each peptide represents a single species of invention in Group I (see claims 52-62 which show the claimed peptides that do not have SEQ ID NO recited in the claims). In Group II each different combination of reagents coupled with different method/process steps represents a different species of invention(claims 63-66). Group III represent a genus of DNA-peptide fusion products that differ in structure, function and biological effects based upon the differing reagents and starting materials used in making them; select a single product for examination (claims 78-81).

The following claim(s) are generic: Group II and III recite generic claims that recite differing species of invention based upon different regents and method steps which result in structurally distinct products.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each species of invention differs in chemical structure, function and biological effect. While the effect claimed is to bind to pertussis toxin, where and how the products bind to pertussis toxin differs based upon chemical structure, thus defining differing species of invention, there not being a common core structure required for each pertussis toxin binding product.

SEQUENCE COMPLIANCE

1. Please see attached Notice to comply and Sequence requirements.

- Applicant's new claims 52, 53, 54, 58, 59, 60, 61, 62 recite amino acid sequences of 4 or more amino acids that must be assigned SEQ ID NOs and have them inserted adjacent to each sequence as an identifier.

- In the instant Specification at page 1, lines 23-24, the four peptides shown at this location must have their SEQ ID NOs assigned and/or inserted adjacent to each amino acid sequence.

- 4. All of the peptide sequences set forth on page 8, lines 7-17 must have their SEQ ID NOs

assigned and/or inserted adjacent to each amino acid sequence.

- The peptide and nucleic acid sequences (10 or more nucleotides) shown on pages 11, 13, 14, 20, 22, 24-27 must have their SEQ ID NOs assigned and/or inserted adjacent to each sequence.

Drawings

6. The drawings are objected to under 37 CFR 1.83(a) because they fail to show SEQ ID NOs for the amino acid sequences in Figure 1A, Figures 3-14. Each SEQ ID NO may be inserted into the Drawings or in the specification's Brief Description of the Drawings in such a way that each sequence shown is clearly identified with a SEQ ID NO.

7. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the

remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GINNY PORTNER whose telephone number is (571)272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginny Portner/
Examiner, Art Unit 1645
November 23, 2009

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645